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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,190	10/28/2003	Lloyd Wolfinbarger JR.	95176562-003002 (64230-00)	3910
7590 Baker & McKenzie Pennzoil Place, South Tower Suite 3400 711 Louisiana Houston, TX 77002			EXAMINER FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/02/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,190	WOLFINBARGER ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 47-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I (claims 1-46) in the reply filed on 6 November 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants also fully responded to the requirement to elect species from generic claims; however, the election of species requirement has been withdrawn, all species have been examined. Claims 1-66 remain pending in the current application, with claims 47-66 being withdrawn from consideration; claims 1-46 have been considered on the merits.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67 is required. Specifically, the current declaration appears to be that from parent application 09/660,422 (now US Patent 6,743,574), however, because the instant application is a continuation-in-part of the parent application, a new oath or declaration is required, pursuant to 37 CFR 1.67(e). The Application Data Sheet is not sufficient to negate the need for the oath or declaration in a continuation-in-part application.

Priority

Acknowledgement is made of applicants claim for priority under 35 USC 120 as a continuation-in-part to prior filed application 09/660,422 (filed 12 September 2000), now US Patent 6,743,574. However, it is noted that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120, as follows:

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The instant application must be an application for a patent for an invention which is also disclosed in the parent application. The disclosure of the invention in the parent application and in the instant application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the parent application, Application No. 09/660,422 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the parent application does not disclose a step of washing the extracted tissue with water which has been passed through a bed of hydrophobic adsorbent resin and anion exchange resin, which is a critical step of each of independent claims 1 and 2. It is noted that the current application is a continuation-in-part of the parent, and thus it is permissible to add new subject matter in the instant application; however, because the subject matter was not disclosed in the parent, its effective filing date, for purposes of determining patentability, is considered to the filing date of the instant application: 28 October 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' claim 1 is directed to a process for preparing a devitalized soft tissue graft for implantation into a mammalian system, comprising:

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(a) extracting a soft tissue sample with an extracting solution comprising one or more non-denaturing detergents, to produce an extracted tissue;

(b) washing said extracted tissue with water which is passed through a bed of hydrophobic adsorbent resin and anion exchange resin;

(c) subsequently, inducing a pressure mediated flow of storage or decontaminating solution comprising one or more decontaminating agents and water replacement agents, through said extracted tissue, to produce said devitalized soft tissue graft; and

(d) storing said tissue in said solution;

wherein said devitalized soft tissue graft retains non-viable cells and/or cellular elements capable of inducing graft repopulation with the appropriate cell type.

In claim 1 what has been identified as step (d), there is insufficient antecedent basis for the limitation "said solution", as there are multiple solutions referenced in the method (e.g. the extracting solution of step (a), and the storage and decontaminating agents of step (c)). Clarification is required.

Applicants' claim 2 is directed to a process for preparing a devitalized soft tissue graft for implantation into a mammalian system, comprising:

(a) inducing a pressure mediated flow of an extracting solution comprising one more non-denaturing detergents, through soft tissue; and

(b) washing said extracted tissue comprising inducing a pressure mediated flow of a water solution through a bed of hydrophobic adsorbent resin and anion exchange resin to produce extracted tissue;

(c) subsequently, including a pressure mediated flow of storage or decontaminating solution comprising one or more decontaminating agents and water replacement agents, through said extracted tissue, to produce said devitalized soft tissue graft; and

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(d) storing said tissue in said storage solution;

wherein said devitalized soft tissue graft retains non-viable cells and/or cellular elements capable of inducing graft repopulation with the appropriate cell type.

In claim 2, what is being identified as step (b), there is not proper antecedent basis for the limitation "said extracted tissue", step (a) does not specifically identify the tissue as 'extracted' at this point. Correction is required.

Furthermore, in claim 2, step (b), it is noted that the claim does not require contact between the water solution and the tissue, but rather only states the washing is achieved by passing water through the resins. It appears the claim should involve a step of washing the tissue *with water that has been* passed through the resin beds. Correction is required.

In both claims 1 and 2, what has been identified as step (c), is considered indefinite because it is not clear what the components of each of the different solutions are. For example, it is not clear if the alternative solutions are:

(i) a storage solution; or (ii) a decontaminating solution comprising one or more decontaminating agents and water replacement agents;

(i) a storage solution and water replacement agents; or (ii) a decontaminating solution comprising one or more decontaminating agents and water replacement agents;

(i) a storage solution comprising one or more decontaminating agents; or (ii) a decontaminating solution comprising one or more decontaminating agents and water replacement agents;

(i) a storage solution comprising one or more decontaminating agents and water replacement agents; or (ii) a decontaminating solution comprising one or more decontaminating agents and water replacement agents;

etc. Clarification is required.

Furthermore, in both claims 1 and 2, what has been identified as step (b) is considered unclear, as the language does not clearly define or particularly point out what type of hydrophobic adsorbent resin or anion exchange resins are required, thus it is not clear how the water is treated (what organics or other molecules are effectively removed by the hydrophobic adsorbent resin, or what anions are changed, and for what). It is noted dependent claims, and the specification, define specific brands (trademarked) of resins which may be used, but each claim must stand on its own, and limitations from the specification cannot be read into the claims.

In claim 4 it is not clear what the processing agents are, thus there is insufficient antecedent basis for this reference. It appears the claim is referring to the non-denaturing detergents.

In claim 14 there is insufficient antecedent basis for the term "said decontaminating water solution" in the first line of the claim. Neither claim 1 or 2 specifically require the decontaminating solution to be a decontaminating *water* solution. Correction or clarification is required.

In claims 15-17, there is insufficient antecedent basis for the term "said water solution" in the first line of each of the claims. Correction is required.

Claim 8 is rejected due to the presence of the trademarks BENZONASE® and PLUMAZYME® in the claim. Claim 18 is also rejected due to the presence of the trademarks XAD and Amberlite™ in the claim. Use of a trademark or trade name in a claim as a limitation to identify or describe a particular material or product, renders the claim indefinite. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 and 29-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. (6,024,735) and Wolfinbarger, Jr. (6,432,712).

The claims are drawn to processes for preparing a devitalized soft tissue graft, comprising:

- (a) extracting a soft tissue sample with an extracting solution, said extracting solution containing a non-denaturing detergent;
 - (b) washing the extracted tissue with water that has been passed through a bed of hydrophobic resin and anion exchange resin; then subsequently
 - (c) washing the extracted tissue with a storage solution or a decontaminated water solution, to produce a devitalized soft tissue graft; and then
 - (d) storing said tissue in storage solution;
- wherein said devitalized soft tissue graft retains non-viable cells and/or cellular elements capable of inducing graft repopulation with the appropriate cell type.

This process may be engaged in using pressure mediated flow per claim 2. Dependent claims recite specific limitations of the contents of the solutions and other parameters.

Both Wolfinbarger, Jr. patents recite processing soft tissue grafts for further implantation into a mammalian system. In both patents, the use of a non-denaturing non-ionic detergent as a first decellularization solution (which applicants call extracting solution) is disclosed. In the '712 patent, decellularization is disclosed as being achieved by extracting the soft tissue graft in a non-denaturing detergent solution potentially containing an endonuclease such as recombinant endonuclease

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(Benzonase™). Recirculation can be done in this step and the '735 patent teaches that pressure mediate flow of any of the solutions used to clean and prepare soft tissue grafts is conventional. After the decellularization steps, both patents disclose washing the decellularized ('extracted') tissue with a washing solution, particularly ultrapure water or other various buffered salt solutions made hypotonic or hypertonic. Absent further definition or evidence to the contrary, the ultrapure water and/or the buffered salt solutions are considered to read on 'water which has passed through a hydrophobic adsorbent resin and anion exchange resin,' and thus use of these solutions to wash the decellularized tissue reads on what is identified as step (b) in the current method. After the washing step, both patents disclose a treatment phase, wherein the decellularized tissue is recirculated with aqueous solutions of morphogens. Following the treatment step, the tissue is washed again with ultrapure water or buffered salt solutions. Both patents teach that decontamination agents may be added to washing solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the disclosed preparation steps with conventional treatments. All of the treatments are known. In absence of objective evidence to the contrary, rearrangement of known treatment steps and optimization of treatment parameters would have been well within the skill of the practitioner at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-65 of U.S. Patent No. 6,743,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because they only differ in that the claims of the instant invention require an additional washing step with water that is indistinguishable over ultrapure water or buffered salt solutions. An additional washing step with commonly known washing solutions (e.g. ultrapure water or buffered salt solutions) is considered a matter of routine optimization, particularly in the instant methods which strive to achieve immunogenic cells and cellular matter from the graft. Therefore, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to perform an additional washing step in the method of US Patent 6,743,574, in order to optimize quality control.

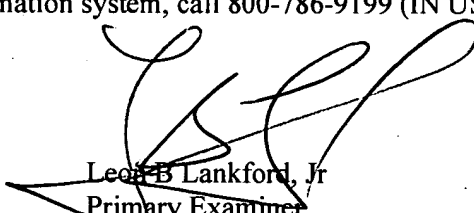
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leonard B. Lankford, Jr.
Primary Examiner
Art Unit 1651